DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0528]

Risk Management; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until May 30, 2003, the comment period for three concept papers entitled "Premarketing Risk Assessment," "Risk Management Programs," and "Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." The document that requested public input, review, and comments for the three concept papers was published in the **Federal Register** of March 7, 2003 (68 FR 11120). The agency is taking this action in response to informal requests for an extension of the comment period.

DATES: Submit written or electronic comments on the concept papers by May 30, 2003.

ADDRESSES: Submit written requests for single copies of the concept paper(s) to Lee Lemley, Executive Operations Staff (HFD–006), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the concept papers.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852, e-mail: FDADockets@oc.fda.gov, or on the Internet at http://accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6218, lemleyl@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

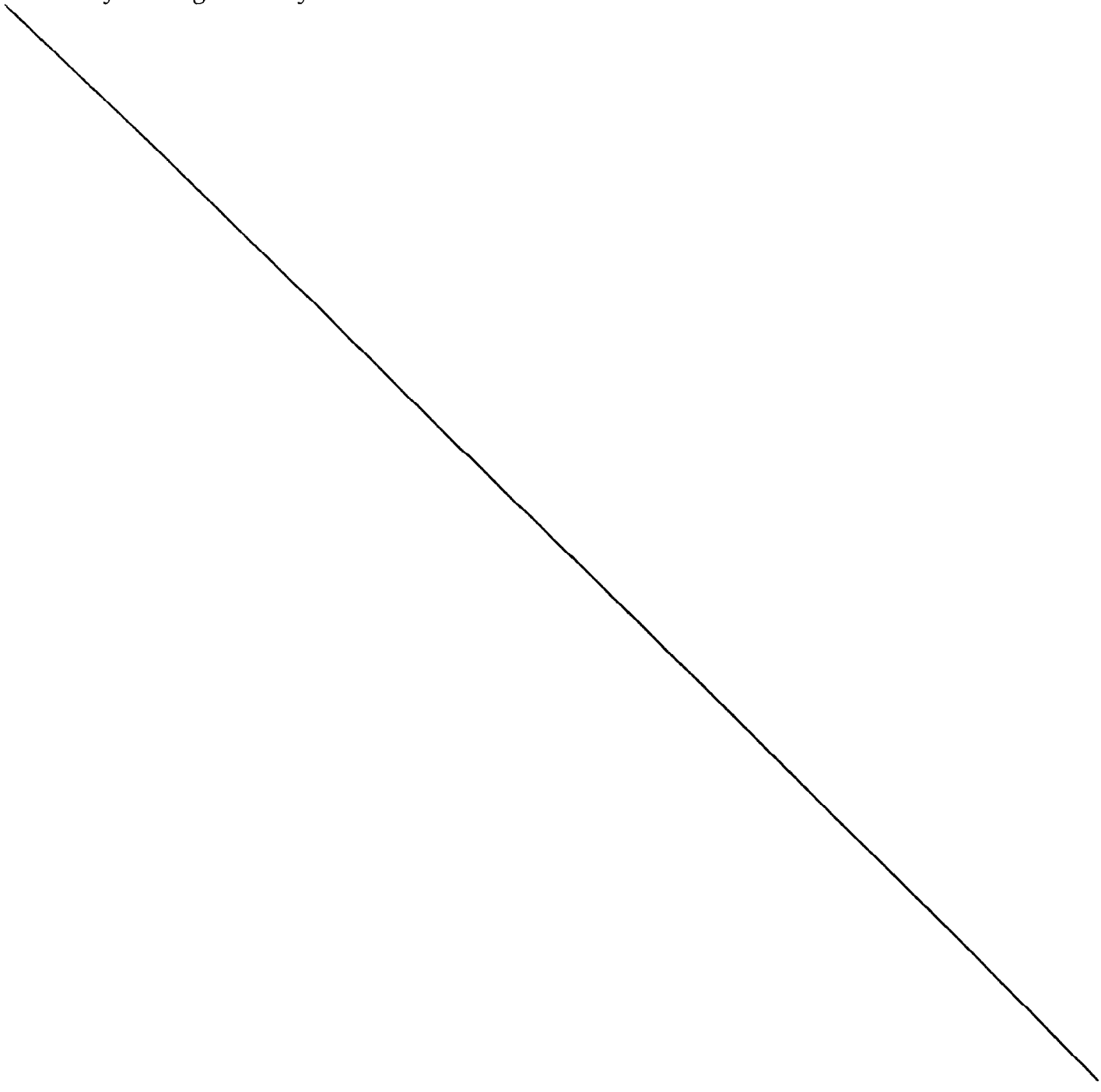
I. Background

In the **Federal Register** of March 7, 2003 (68 FR 11120), FDA published a document announcing a public workshop to discuss risk management activities for drug and biological products (excluding blood products other than plasma derivatives). The public workshop was held, as scheduled, on April 9, 10, and 11, 2003. To facilitate public input and discussion, FDA simultaneously had issued three concept papers for review and comment entitled: (1) "Premarketing Risk Assessment," (2) "Risk Management Programs," and (3) "Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment." Interested persons were given until April 30, 2003, to submit written or electronic comments on the concept papers. In response to informal requests from interested persons for additional time to submit comments on the concept papers, FDA has decided to reopen the comment period until May 30, 2003.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the concept papers. You should annotate and organize your comments to identify the specific concept paper and issue to which the comments refer. Where possible, comments should

reference line numbers in the concept papers. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The concept papers and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.



III. Electronic Access

Electronic versions of the concept papers are available via the Internet at http://www.fda.gov/cder/meeting/riskmanagement.htm.

Dated: MAY 2 2003
May 2, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S